The effect of light and/or melatonin on sleep, mood, cognition and behavior in demented elderly.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28032

Source
NTR

Brief title
Light and melatonin in dementia

Intervention

Outcome measures

Primary outcome

Before starting the suppletion of light and melatonin all subjects were tested for their rest-activity rhythm by actometry, 24-hour salivary melatonin and cortisol levels were measured as was the 24-hour ear temperature. Neuropsychological assessment was done to test cognitive abilities and dementia severity and caregivers were asked about mood, behavior, sleep and abilities in activities of daily living of the subjects. All these measures are again tested 6 weeks after the start of the change in light and the suppletion of melatonin, to test the relatively short-term effects on changes in rest-activity, rhythmicity of endogenous melatonin, cortisol and temperature rhythm and alterations in mood and behavior. The long-term effects are tested every 6 months after the start of light and melatonin as long as a subject participates in the study with a maximum of 3.5 years.

Secondary outcome

Before starting the suppletion of light and melatonin all subjects were tested for their rest-activity rhythm by actometry, 24-hour salivary melatonin and cortisol levels were measured as was the 24-hour ear temperature. Neuropsychological assessment was done to test cognitive abilities and dementia severity and caregivers were asked about mood, behavior, sleep and abilities in activities of daily living of the subjects. All these measures are again tested 6 weeks after the start of the change in light and the suppletion of melatonin, to test the relatively short-term effects on changes in rest-activity, rhythmicity of endogenous melatonin, cortisol and temperature rhythm and alterations in mood and behavior. The long-term effects are tested every 6 months after the start of light and melatonin as long as a subject participates in the study with a maximum of 3.5 years.

Study description

Background summary

A large proportion of the demented elderly show fragmented sleep-wake patterns and disturbed circadian rhythms. It appears that the amplitude of the circadian rhythms is attenuated with age, with an exaggerated decline in demented elderly. Decreased input of entraining stimuli, due to diminished stimulation by environmental light and by lower levels of the pineal hormone melatonin to the suprachiasmatic nucleus (SCN), the pacemaker of the circadian timing system, might contribute to these disturbances. To test this we changed the lights in the common room of 12 different homes for the elderly. Half of them got lights with an intensity of about 1200 lux, half of them got lights of the same intensity they had before, and functions as a placebo condition. In the evening all participants get a tablet with either 2.5 mg melatonin or placebo approximately one hour before bedtime. Before starting the suppletion of light and melatonin all subjects were tested for their rest-activity rhythm by actometry, 24-hour salivary melatonin and cortisol levels were measured as was the 24-hour ear temperature. Neuropsychological assessment was done to test cognitive abilities and dementia severity and caregivers were asked about mood, behavior, sleep and abilities in activities of daily living of the subjects. All these measures are again tested 6 weeks after the start of the change in light and the suppletion of melatonin, to test the relatively short-term effects on changes in rest-activity, rhythmicity of endogenous melatonin, cortisol and temperature rhythm and alterations in mood and behavior. The long-term effects are tested every 6 months after the start of light and melatonin as long as a subject participates in the study with a maximum of 3.5 years. The endpoint for participating in the study is set at the moment that a subject changes from the participating home for the elderly to a nursing home or when a subject passes away. So far hopeful results have been found for light and melatonin in relatively small groups of patients. We now want to test the effect in a large group of patients to be able to differentiate the effects according to different subject related co-variables and to test the combination of light and melatonin.

Study objective

So far hopeful results have been found for light and melatonin in relatively small groups of

patients. We now want to test the effect in a large group of patients to be able to differentiate the effects according to different subject related co-variables and to test the combination of light and melatonin.

Intervention

Ceiling mounted indirect bright light (1000 lux in gaze direction) or ceiling mounted placebo light (300 lux in gaze direction), 6 homes in each condition.
Furthermore, all participants were randomized to melatonin (2.5 mg) or placebo, daily administered 1 hour before bedtime.

Contacts

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Eligibility criteria

Inclusion criteria

Demented elderly, living in the assisted care facilities of 12 different homes for the elderly in different places in the Netherlands.

Exclusion criteria

N/A

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-1999
Enrollment:	189
Type:	Actual

Ethics review

Positive opinion

Date:	23-05-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL54
NTR-old	NTR83
Other	: ZON-MW no: 28-3003
ISRCTN	ISRCTN93133646

Study results

Summary results
JAMA. 2008 Jun 11;299(22):2642-55.